See also Vol. 3190

No. 18,139

United States Court of Appeals

For the Ninth Circuit

UNITED STATES OF AMERICA,
Libelant-Appellant,

vs.

1200 CANDY BARS, MORE OR LESS, LABELED IN PART "STA-TRIM,"
Defendant-Respondent,

and

STA-TRIM CONFECTIONS, INC.,
Claimant-Appellee.

Appeal from the United States District Court, Northern District of California, Southern Division. Honorable William T. Sweigert, Presiding.

APPELLANT'S REPLY BRIEF

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SUBJECT INDEX

TABLE OF AUTHORITIES CITED

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APPELLANT'S REPLY BRIEF

Appellee exhibits in its brief a most regrettable inaccuracy in the statement of facts. It utilizes the technique of drawing erroneous conclusions from erroneous premises. It sets up straw men and then demolishes them. We are therefore obliged, in this Reply Brief, to call the Court's attention to several major examples of this propensity.

1. Contrary to Appellee's Implication, the Government's Position Here Is Consistent With the Administrative Interpretation of Section 342(d) Maintained by the Food and Drug Administration Since the Enactment of That Section.

The following quotation is taken from page 13 of Appellee's brief and is a good illustration of the technique alluded to above:

> "It is not without significance to note that since the enactment of Section 342(d), the Food and Drug Administration has itself applied this section only to nonnutritive substances which were inedible or harmful. For example, this section has been applied to the use in confectionery of such nonnutritive substances as carnauba wax, shellac and sodium bisulphite. [Food and Drug Administration Trade Correspondence 317, August 20, 1940; Food and Drug Administration Trade Correspondence 238, April 11, 1960; (both reported in CCH Food, Drug and Cosmetic Act Reporter).] However, in the case of stearic acid, the Food and Drug Administration has ruled that Section 342(d) does not apply since stearic acid is an *edible* nonnutritive substance. (Food and Drug Administration Trade Correspondence 238, April 11, 1940.)"

In this paragraph, Appellee seeks to create the impression that the Food and Drug Administration has heretofore taken the position now espoused by Appellee and has deemed Section 342(d) to apply only to nonnutritive substances which are *inedible or harmful.* Nothing could be further from the truth as we will demonstrate shortly. To prove its point, Appellee *paraphrases* an administrative interpretation of this section with respect to stearic acid as a ruling "*that Section 342 (d) does not apply since stearic acid is an edible non-*

nutritive substance." So that the Court may have a true picture, we quote the relevant portion of this administrative interpretation as it is reported in *Kleinfeld and Dunn,* Federal Food, Drug, and Cosmetic Act 1938-1949, pages 662-3 (CCH 1949):

> "Correspondent asks whether it is permissible to coat confectionery with edible grades of stearic acid.
>
> "'*The prohibition* in Section 402(d) of the Act [21 U.S.C. 342(d)] against glaze in confectionery in excess of 0.4 per cent *applies only to a nonnutritive substance.* In the case of edible stearic acid, the 0.4 per cent limitation would not apply, since it is not a resinous glaze *nor is it nonnutritive.* Its addition to confectionery would, however, be subject to the general provisions of the Act. . . .'" (Emphasis added.)

In the foregoing statement, the Food and Drug Administration unequivocally declared that stearic acid is *not* a nonnutritive substance. Yet Appellee paraphrases this statement to convey the opposite meaning. Why does Appellee do this? To give emphasis to the word "edible" so as to create the false impression that the Food and Drug Administration has construed Section 342(d) to apply only to nonnutritive substances which are inedible or harmful.

There are various grades of stearic acid, some of which are suitable for human consumption and some of which are less pure and are therefore suitable only for industrial uses such as in the production of candles, phonograph records, insulators, modeling compounds, etc. See *The Merck Index* (Seventh Edition, 1960), pages 976-7. Obviously, confectionery is a food which

should contain only edible substances, but the applicability of Section 342(d) hinges exclusively upon the *nonnutritive quality* of the substances or the presence of alcohol. Another provision of the law deals specifically with foods which are unfit for human consumption. [21 U.S.C. 432(a)(3).]

In the above quoted statement from page 13 of Appellee's brief, there is also reference to carnauba wax, shellac, and sodium bisulphite with the implication that these substances are excluded from confectionery through the operation of Section 342(d) because they are inedible and harmful as well as nonnutritive. This is not true. Insofar as these substances are excluded by Section 342(d), the sole test is their nonnutritive character, except that the statutory exemption for glaze specifies that the glaze must be "harmless." We quote the administrative rulings as reported in *CCH Food, Drug, Cosmetic Law Reporter,* page 3198, paragraph 3036:

Carnauba Wax

> "So far as we are aware, carnauba wax is to be classed as a nonnutritive substance under the new Food, Drug, and Cosmetic Act, and since it is not included in the list of exempted nonnutritive articles in Section 402(d) of the Act, it will not be a proper ingredient of confectionery under the new Act." TC-238, April 11, 1940.

Shellac

> "Under section 402(d)confectionery may contain harmless resinous glaze not in excess of four-tenths of one percentum. Shellac used in confec-

tionery is classed as a harmless resinous glaze, provided it is free from poisonous or deleterious impurities." . . . TC-238, April 11, 1940.

Sodium Bisulphite

". . . Since that time further consideration has been given to the status of sodium bisulphite in confectionery and the conclusion reached that this chemical is a nonnutritive substance and, therefore, under the provision of section 402(d) of the Food, Drug, and Cosmetic Act may not be used in confectionery in any amount." TC-317, August 20, 1940.

These rulings speak for themselves and clearly belie Appellee's assertions.

2. The Government Does Not Disavow the Testimony of Mr. Campbell.

In our opening brief (pages 21-25), we referred to the legislative history of Section 342(d), citing the testimony of Mr. Campbell who was then the Chief of the Food and Drug Administration to support our position that when Congress used the term "nonnutritive substance" it meant just that, nothing more or less. We also cited unsuccessful efforts made by Mr. Heide, a representative of the confectionery industry, to cut down the scope of the confectionery provisions of the bill then before Congress. Mr. Heide's suggestions show that he completely agreed with Mr. Campbell that the exclusion of nonnutritive substances from confectionery would be absolute, and he therefore proposed the use of more limiting language.

However, on page 12 of Appellee's brief, *after quot-*

ing only portions of Mr. Campbell's relevant testimony, there appears the following statement with reference to this segment of the legislative history:

> "In the first place, *it is disturbing* to say the least, that the appellant seeks to disavow the very explicit statement of its own Chief of the Food and Drug Administration with reference to the meaning of 'nonnutritive substance' and to rely upon the statement of one who was neither a proponent nor draftsman of the bill." (Emphasis added.)

Appellee is needlessly disturbed since the Government does not disavow Mr. Campbell's testimony but relies on *all* of it, including the portion overlooked by Appellee where Mr. Campbell urged a special exemption for chewing gum lest it become an illegal product because of the all-inclusive ban against any nonnutritive substance. (See page 22 of our opening brief.)

3. The Government's Interpretation of Section 342(d) Is Not in Conflict With Section 343(j).

On pages 15-18 of Appellee's brief, the assertion is made that the Government's interpretation of Section 342(d) is in conflict with Section 343(j). Through Section 343(j) and the regulations authorized thereunder (21 CFR § 125), Congress has undertaken to regulate the labeling of foods which are promoted for special dietary uses -- i.e., infant foods, low sodium foods, foods used in control of body weight or in dietary management with respect to disease, foods containing nonnutritive constituents, etc.

Section 343(j) reads:

> "A food shall be deemed to be misbranded if it purports to be or is represented for special dietary

> uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses."

The purpose of this Section is fully to inform purchasers of special dietary foods as to the real value of the foods for the purposes for which they are offered. Obviously, it is designed to help prevent consumer deception, not to foster and facilitate it.

By this statute and the regulations promulgated under it, general provision is made for the marketing of certain classes of food containing nonnutritive constituents. (See 21 CFR § 125.7 and § 1.11.) But through Section 342 (d), Congress has declared that confectionery shall not contain nonnutritive substances, *regardless of whether it is offered as a special dietary food.*

Appellee cites *U. S. v. 62 Cases of Jam,* 340 U.S. 592 (1951). There the issue was whether a product which purported to be jam but did not conform to the administrative standard for jam could legally be marketed under the name "Imitation Jam." The Court held that one section of the law [403(c)] expressly authorized use of the "Imitation" label on *any* food which imitated another, and that there was no provision which expressly prohibited use of the "Imitation" label on a food which imitated a standardized food. On page 600, the Court said:

> "We could hold it to be 'misbranded' only if we held that a practice Congress authorized by § 403 (c) Congress *impliedly* prohibited by § 403(g)." (Emphasis added.)

In other words, the general authorization in one section of the law to use the "Imitation" label could not be curtailed by an *implied* prohibition in another section of the law. But the Supreme Court went on to say that it was within the power of Congress to cut down the scope of the general authorization by an *express* limitation:

> "If Congress wishes to say that nothing shall be marketed in likeness to a food as defined by the Administrator, though it is accurately labeled, entirely wholesome, and perhaps more within the reach of the meager purse, *our decisions indicate that Congress may well do so. But Congress has not said so.*" (Emphasis added.)

In the instant case, on the other hand, Congress has affirmatively chosen to deal with the composition of confectionery in Section 342(d) and has *expressly* excluded nonnutritive substances from confectionery. In Section 343(j) Congress generally authorized the marketing of foods with special dietary properties, but in Section 342(d) Congress specifically prohibited the use of nonnutritive ingredients in confectionery, whether or not the confectionery is dressed up as a food "for special dietary uses." This is clearly within the Congressional power under the *Jam* case, *supra*. See also *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218 (1943), and *Carolene Products Co. v. U. S.*, 140 F.2d 61, 65 (C.A. 4, 1944), affirmed 323 U.S. 18 (1944).

Consequently, when the administrative regulations under Section 343(j) state that the regulations dealing with nonnutritive constituents do not relieve any food from complying with Section 342(d) or other provisions

of the law (21 CFR 125.7), they merely call attention to a policy which *Congress* enacted into law. The classification distinguishing confectionery from other foods was made by Congress and not by the administrative body.

4. Sta-Trim Candy Bars Are Not Low Calorie Products.

On pages 15-20 of its brief, Appellee repeatedly refers to the Sta-Trim bars under seizure in this case as low calorie confections and low calorie candies, despite the District Court's adjudication that the term "low calorie" is false and misleading when applied to these candy bars.

In the Decree of Condemnation, the District Court said in part (R. 90):

> "ORDERED, ADJUDGED AND DECREED that the said article under seizure is in violation of 21 U.S.C. 343(a) and (g) as alleged in the Amended Libel, and is therefore hereby condemned pursuant to 21 U.S.C. 334(a) . . ."

And the Amended Libel alleged in part (R. 15):

> "The aforesaid article was misbranded when introduced into and while in interstate commerce within the meaning of said Act, as follows:
>
> "*21 U.S.C. 343(a)* in that the label statements 'Low Calorie,' 'Good for you when you diet—Good for you when you want to keep trim,' and 'For People Who Want To Keep Trim,' are false and misleading since the article is not low in calories and will not be effective to reduce weight or to keep trim . . ."

Since Appellee is not challenging the District Court's djudication that the product is misbranded as alleged,

it has no basis whatsoever for using the term "low calorie" to describe its product.

5. Appellee's References to the Question of an Interlocutory Appeal Are Confusing.

In the Court below, there were three different rulings with respect to whether an interlocutory appeal was appropriate at an early stage of the proceeding. Those rulings have no bearing on the present appeal. Yet Appellee on page 4 of its brief chooses to quote from the first of those rulings, knowing that the District Court subsequently set that ruling aside. To clear up any possible misconceptions, we think it best to cite all of the Court's rulings on this point:

R. 78

> "This lawsuit would not be ended even if summary judgment were entered in favor of libelant on the issue of adulteration. There still remains the issue of misbranding which involves questions of fact to be tried. The adulteration issue does not present a controlling question of law because both issues are separate and independent of each other. For these reasons, the Court is unable to certify this matter to the appellate court under Section 1292 (b)."

R. 83

> "Upon further consideration, however, it appears that a summary judgment in favor of libelant on the issue of adulteration would dispose of the case."

R. 84

> "The Court is of the opinion that its ruling on the adulteration issue involves a controlling ques-

tion of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order to be entered thereon may materially advance the ultimate termination of the litigation."

R. 85-86

"IT IS THE FURTHER ORDER of this Court, in view of the strong policy against piecemeal appeals, and because the remaining issue of misbranding may be tried in several days, that the Supplemental Opinion of this Court, dated July 12, 1961, indicating the Court's willingness to certify this matter for an interlocutory appeal under Section 1292(b) of Title 28, United States Code, be set aside, and this matter proceed to trial forthwith."

The arguments made in Appellee's brief are irrelevant and without merit. Again we urge that this Court take the course of action proposed on pages 38 and 39 of our opening brief.

Respectfully submitted,

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CERTIFICATE

I certify that, in connection with the preparation of this brief, I have examined Rules 18 and 19 of the United States Court of Appeals for the Ninth Circuit, and that, in my opinion, the foregoing brief is in full compliance with those rules.

_____

Attorney.